CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 9 **CX/RVDF 10/19/9**

May 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOD

Nineteenth Session

Burlington, Vermont, United States of America, 30 August - 3 September 2010

RISK MANAGEMENT RECOMMENDATIONS FOR VETERINARY DRUGS FOR WHICH NO ADI AND MRL HAS BEEN RECOMMENDED BY JECFA

(Report of the electronic Working Group on Risk Management Recommendations/Guidance for Veterinary Drugs for Which no ADI and MRL has been Recommended by JECFA)

(Argentina, Australia, Belgium, Brazil, Canada, European Union, France, Germany, Iran, Japan, Poland, Republic of Korea, Sweden, United States of America, JECFA and IFAH)

1. At the last (18th) session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF – Natal, Brazil, 11-15 May 2009), the Committee recalled that at its 17th session (CCRVDF – Breckenridge, Colorado, USA; 3-7 September 2007) they forwarded a project document on Risk Management Recommendations for Veterinary Drugs without ADI and/or MRLs to the 31st Session of the Codex Alimentarius Commission (Commission) for approval as new work for the Committee; and that the Commission noted a proposal to revise the project document to broaden the scope of new work on risk management decisions to also include substances for which no ADI and/or MRL were set because the information needed to evaluate human health concerns was lacking or incomplete. In view of the substantial change in the scope of the proposal, the Commission decided to return the proposed new work back to the CCRVDF for further consideration.

2. The EWG has considered the charge provided by the 18th CCRVDF and has the following recommendations. This document reflects the input from the following countries and organizations: Belgium, Brazil, Canada, Germany, Japan, Sweden, IFAH, JECFA, European Commission, and United States of America.

Charge 1. Define the scope for the new work addressing risk management recommendations for veterinary drugs for which no ADI and MRL has been recommended by JECFA due to specific human health concerns or lack of information needed to resolve existing human health concerns

3. The scope of the new work should be to provide risk management advice to national and regional authorities on veterinary drugs for which acceptable daily intakes (ADI) and maximum residue limits (MRL) for veterinary drugs cannot be recommended because (1) the JECFA risk assessment identifies specific human health concerns that prevent such determination or (2) insufficient data are available to resolve existing human health concerns.

4. For certain veterinary drugs, JECFA is not able to establish an ADI or recommend MRLs, either due to specific human health concerns (e.g., toxicity to the human consumer) or due to insufficient available data for the risk assessment. It is therefore proposed that CCRVDF should make risk management decisions on those veterinary drugs and provide risk management recommendations to Codex members. The objective is to protect consumers from potentially unsafe residues and provide risk management guidance that will facilitate international trade.

5. The JECFA ADI and Codex MRL provide clear guidance to Codex members on the safety veterinary drug residues in food. In the absence of the Codex standard, CCRVDF can contribute to public health by providing risk management recommendations that take into account information available from the JECFA risk assessment and other relevant sources based on science. Providing clear risk assessment information by JECFA coupled with clear risk management recommendations by CCRVDF would be particularly to helpful countries without the sufficient capacity to perform independent risk assessments.

6. It is important that CCRVDF have available a wide range of risk management strategies and options when dealing with veterinary drugs for which no ADI or MRL has been established. It is recommended that CCRVDF undertake to consider the broad scope of possible risk management recommendations. This work would include, risk management options, how best to communicate to the public and to national regulatory authorities, and how the risk management information provided should be interpreted. For example, it is recognized that there are some veterinary drugs for which the data are not, and are not likely to become, available for conventional evaluation by the JECFA. JECFA may be able in some circumstances to establish a threshold of toxicological concern and provide this information to CCRVDF. In these circumstances, it may be advisable for CCRVDF to work with JECFA to develop a process where CCRVDF establishes a threshold of regulatory concern for veterinary drugs. This threshold of regulatory concern would be based on toxicological, residue (metabolism) and exposure data, taking into account feasible and practicable analytical method performance, and establish an internationally agreed threshold of toxicological concern (i.e., a default limit) for the risk management of such drugs.

7. There may be some veterinary drugs for which an ADI or MRL has not been established but for which a source cannot be identified to provide the necessary information for a JECFA evaluation leading to an ADI and recommended MRLs. While the threshold of toxicological concern is one approach, it may be advisable for the CCRVDF, possibly in consultation with the JECFA secretariats, to engage in a discussion to identify other alternative mechanisms to provide national or regional authorities with the information necessary to make risk management decisions. For example, the possible utility of regional or national MRLs used as a basis for Codex MRLs in such circumstances was discussed at the Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs Without ADI/MRL (Bangkok, Thailand, 2004) and at subsequent CCRVDF meetings. Additional discussion may illuminate practical alternatives.

Charge 2. Develop a process by which the Committee will promulgate risk management recommendations.

8. It is recommended that CCRVDF construct a system of policies and procedures that are found acceptable by the Commission that would be used to develop and communicate risk management recommendations from CCRVDF for veterinary drugs in which JECFA was unable to establish an ADI or recommend an MRL. CCRVDF will need to discuss and reach consensus on:

Principles to guide selection of veterinary drugs for risk management recommendations.

9. It is recommended that the scope of the Priority List of Veterinary Drugs Requiring Evaluation or Reevaluation by JECFA be expanded. In general, veterinary drugs are included for consideration on the priority list in order to request that JECFA determine an ADI and recommend MRLs.

10. Some exceptions have occurred recently (e.g. malachite green) where the task for the risk assessment was to make a recommendation to the CCRVDF risk managers (request to JECFA to consider the literature review and advise if this substance can be supported for use in food producing animals) rather than to recommend MRLs. Similarly, a risk assessment by the 62nd JECFA conducted for the veterinary drug chloramphenicol that concluded the low concentrations of chloramphenicol found in food monitoring programs in the year 2002 could not originate from residues of chloramphenicol persisting in the environment after historical veterinary uses of the drug in food producing animals and that it is not appropriate to establish an ADI for chloramphenicol.

11. It is recommended veterinary drugs be included in the priority list for the purpose of obtaining expert advice to assist in risk management decisions in circumstances where an MRL may not be possible.

12. It is further recommended that the ad hoc working group on priorities develop guidelines for prioritization of drugs for which the JECFA is unable to establish ADI or recommend MRLs, similar to those developed when the purpose is for the JECFA to establish an ADI and recommend MRLs.

Process by which the Committee will understand the basis on which an ADI and/or an MRL could not be established; based on human health concern, lack of information or because JECFA has completed an assessment but for which CCRVDF has not developed risk management recommendations.

13. In order to accomplish these steps, it is recommended that when CCRVDF receives a JECFA assessment that determines either that an ADI may not be established or that MRLs cannot be recommended, a physical or electronic ad-hoc working group is established to evaluate the risk management options that are available. Depending on the nature of the veterinary drug(s) under consideration and the complexity of the issue, the ad-hoc working group may need to operate between sessions. The ad-hoc working group should:

14. Understand whether the JECFA was unable to establish an ADI or recommend an MRL due to a lack of information or a specific human health concern. This information is available in the JECFA report and through consultation with the JECFA secretariats.

15. If the basis for JECFA not establishing an ADI or recommending an MRL was due to a lack of information, consider whether there is a potential to obtain the missing information, and if so, how that may be accomplished. It is recommended that working group consider innovative mechanisms to obtain the missing information. For example, are there ways to encourage submission of data used to establish regional or national MRLs to be included in the JECFA evaluation?

16. Alternatively, the working group may determine that it is not possible or practical to obtain the requested information and develop risk management recommendations based on the information available.

17. If the basis for JECFA not establishing an ADI or recommending an MRL was because a specific human health concern, the working group will need to consider the complete description of the human health concern in the context of the totality of the JECFA risk assessment and develop risk management recommendations to Codex members,

18. Upon consideration of all available information, the ad-hoc working group will then provide a risk management recommendation(s) to the CCRVDF. (See flowchart of the Proposed Risk Management Approach).

Charge 3. Make proposals on how to address the remaining veterinary drugs for which JECFA clearly identified human health concerns listed in Annex II of CX/RVDF 09/18/8.

19. It is recommended that these veterinary drugs be referred to the process identified in charge 2 above, starting at the appropriate point. The current eWG considers these drugs to be:

Carbadox	Chloramphenicol*	Chlorpromazine
Malachite Green*	Nitrofurans	Nitroimidazoles
Olaquindox	Stilbenes (Diethylstilbestrol)	

*The 18th CCRVDF stated that these veterinary drugs should not be used in food producing animals.

Charge 4. Propose procedures for conveying these risk management recommendations in the Codex standard setting process.

20. The JECFA ADI and Codex MRL provide clear risk management guidance to Codex members on the safety of veterinary drug residues in food. In the absence of the Codex standard, CCRVDF can contribute to public health by providing risk management recommendations that take into account information available from the JECFA risk assessment and other relevant sources based on science. Information is currently provided through the reports of the JECFA, the reports of the CCRVDF, and the reports of the Codex Alimentarius Commission. The FAO (http://www.fao.org/ag/agn/jecfa-additives/search.html) and WHO (http://apps.who.int/ipsc/database/evaluations/search.aspx) have recently made improvements to the websites that provide the results of the JECFA evaluations. The Codex Alimentarius (http://www.codexalimentarius.net/vetdrugs/data/index.html) has also improved the Codex Veterinary Drug Residues in Food Online Database website providing the standards for residues of veterinary drugs in foods. The changes to these three websites have greatly improved clarity and transparency.

21. As currently presented, the Codex Alimentarius website, incorporating links to the JECFA reports and monographs, provides a comprehensive presentation of the risk assessments and risk management recommendations (e.g., Codex Maximum Residue Limits) for those veterinary drugs that have completed the Codex Step Process.

22. The process described above in Charge 2 would allow risk management recommendations for veterinary drugs for which an ADI or MRLs could not be established to progress through the Codex Step Process and be presented on the revised Codex Alimentarius website.

23. The proposal will allow the consolidated presentation of risk management recommendations for residues of veterinary drugs in food that would be more useful to Codex member risk managers. The proposal will result in all veterinary drugs that have been evaluated by JECFA and CCRVDF to progress through the Codex Step Process. The risk management recommendations may then be presented on the Codex website and available to regional/national authorities and the general public.

24. Inclusion of information on the Codex Veterinary Drug Residues in Food website requires that information to have completed the Codex Step Process. As a consequence, veterinary drugs evaluated by JECFA that do not have a temporary or permanent Codex MRL would not be included on the website unless the risk management recommendations provided by CCRVDF had proceeded through the Codex Step Process. Similarly, national or regional authority MRLs or recommendations which might be proposed to provide risk management guidance in the absence of JECFA recommended MRLs could not be included unless they have also proceeded through the same Step Process.

25. Risk management recommendations are already provided in the Codex Veterinary Drug Residues in Food Online Database in the form of the Codex MRLs (which are also standards). The JECFA provides information that would contribute to risk management decisions, and sometimes offers risk management advice by CCRVDF, in their reports. Incorporation of additional risk management advice, particularly for those veterinary drugs for which an ADI or MRL cannot be established, could be presented directly in the database report, or the report could provide a link to a separate CCRVDF document.

26. A Flow Chart of the Proposed Risk Management Approach.